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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/499,006	02/04/2000	Dr. Paddy Jim Baggot	249/127	9604

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EXAMINER

JOHANNSEN, DIANA B

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b>	<b>Application No.</b> 09/499,006	<b>Applicant(s)</b> BAGGOT, DR. PADDY JIM	
	<b>Examiner</b> Diana B. Johannsen	<b>Art Unit</b> 1634	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 09 January 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. **ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).**

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.
- NOTE: See Attachment.
3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance ~~because~~: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: none.

Claim(s) objected to: none.

Claim(s) rejected: 15, 16 and 18-24.

Claim(s) withdrawn from consideration: 1 and 17.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

Continuation of 5. does NOT place the application in condition for allowance ~~because~~: for the reasons set forth on the Attachment to this Advisory Action and for the reasons of record in view of the non-entry of the After Final Amendment.

## **ATTACHMENT TO ADVISORY ACTION**

### ***Amendment Format***

1. Regarding the claim set filed with the Amendment After Final of January 9, 2004, it is noted that the status identifiers provided for claims 1, 16, and 17 are incorrect. Particularly, claims 1 and 17, which are withdrawn, are indicated as being "Previously Presented," and claim 16, which was previously presented, is indicated as being "New." Because Applicant's amendment does not comply with 37 CFR 1.121(c), it cannot be entered. However, because the instant application is after final, and in the interest of compact prosecution, the examiner has reviewed the Amendment in order that Applicant may be informed of other reasons the Amendment would not entered if it were compliant in form (see below). Applicant is reminded of the requirements of 37 CFR 1.121(c). Amendments to the claims filed on or after July 30, 2003 must comply with 37 CFR 1.121(c) which states:

(c) *Claims*. Amendments to a claim must be made by rewriting the entire claim with all changes (e.g., additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered).

(1) *Claim listing*. All of the claims presented in a claim listing shall be presented in ascending numerical order. Consecutive claims having the same status of "canceled" or "not entered" may be aggregated into one statement (e.g., Claims 1-5 (canceled)). The claim listing shall commence on a separate sheet of the amendment document and the sheet(s) that contain the text of any part of the claims shall not contain any other part of the amendment.

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(2) *When claim text with markings is required.* All claims being currently amended in an amendment paper shall be presented in the claim listing, indicate a status of "currently amended," and be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. Only claims having the status of "currently amended," or "withdrawn" if also being amended, shall include markings. If a withdrawn claim is currently amended, its status in the claim listing may be identified as "withdrawn—currently amended."

(3) *When claim text in clean version is required.* The text of all pending claims not being currently amended shall be presented in the claim listing in clean version, *i.e.*, without any markings in the presentation of text. The presentation of a clean version of any claim having the status of "original," "withdrawn" or "previously presented" will constitute an assertion that it has not been changed relative to the immediate prior version, except to omit markings that may have been present in the immediate prior version of the claims of the status of "withdrawn" or "previously presented." Any claim added by amendment must be indicated with the status of "new" and presented in clean version, *i.e.*, without any underlining.

(4) *When claim text shall not be presented; canceling a claim.*

(i) No claim text shall be presented for any claim in the claim listing with the status of "canceled" or "not entered."

(ii) Cancellation of a claim shall be effected by an instruction to cancel a particular claim number. Identifying the status of a claim in the claim listing as "canceled" will constitute an instruction to cancel the claim.

(5) *Reinstatement of previously canceled claim.* A claim which was previously canceled may be reinstated only by adding the claim as a "new" claim with a new claim number.

### ***New Issues Raised***

2. Applicant's proposed amendments raise the following new issues under 35 USC 112, second paragraph that would require further consideration. Regarding claim 15 and claims dependent therefrom, Applicant has proposed amending claim 15 to recite "identifying the presence of Down Syndrome in the fetus when a pattern of the quantity of each metabolite in the amniotic fluid specimen differs from a pattern of in the quantity of each metabolites in the control profile." It is unclear as to what might be considered a

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“pattern of the quantity of each metabolite,” and as to how a “pattern of the quantity” of a metabolite would differ from the quantity of the metabolite (i.e., does the claim require a comparison of quantities, or of some particular feature or “pattern” of each quantity?).

As a result of applicant’s proposed amendments to claim 15, there is insufficient antecedent basis for the recitation “the subset of metabolites” in claim 16. Regarding claim 21 and claims dependent therefrom, Applicant has proposed amending claim 21 to recite “identifying the presence of Down Syndrome in the fetus when a pattern of the quantity of each metabolite in the profile of the amniotic fluid specimen corresponds to a pattern of the quantity of each metabolites in amniotic fluid a fetus with Down Syndrome.” It is unclear as to what might be considered a “pattern of the quantity of each metabolite,” and as to how a “pattern of the quantity” of a metabolite would differ from the quantity of the metabolite (i.e., does the claim require a comparison of quantities, or of some particular feature or “pattern” of each quantity?). In claim 22, the recitation “the pattern the quantity of each metabolite” is indefinite, as this language does not make clear whether the claim further limits a previously recited “pattern” or a previously recited “quantity.” As a result of Applicant’s proposed amendments to claim 21, there is insufficient antecedent basis for the limitation “the patient profile” in claim 22. In claim 23, the recitation “the pattern plurality of the quantity of each metabolite” is indefinite, because the claims do not previously refer to a “pattern plurality,” and because it is not clear what the claim further limits. There is also insufficient antecedent basis for the limitation “the patient profile” in claim 23.

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3. Applicant's proposed amendments also raise the following new grounds for objection: in claim 15, the recitations "amniotic fluid specimen that, lists each metabolite" (rather than, e.g., "amniotic fluid specimen that lists each metabolite") and the recitation "pattern of in the quantity of each metabolites in the control profile"; in claim 21, the recitation "each metabolites in" and the recitation "in amniotic fluid a fetus with Down Syndrome" (rather than, e.g., "in amniotic fluid of a fetus with Down Syndrome").

***Claim Rejections - 35 USC § 112, first paragraph***

4. Regarding the rejection of record of claims 15-16 and 18-24 under 35 USC 112, first paragraph, Applicant argues that the data presented in the specification was obtained "from the amniotic fluid of fetuses who have been born and conclusively diagnosed later as 'patients' with Down Syndrome" and that the term "patient" is used in the specification in a manner that "is ordinary practice in the field when referring to data obtained from amniotic fluid, even though a subsequent diagnosis may be made post-partum." The response further states that "Applicant has extensive data that could be provided by declaratory evidence that the amniotic fluid obtained from a fetus may be used in comparison with a profile of control group, i.e., healthy babies, to diagnose Down Syndrome" and that "Applicant is readily capable of providing declaratory data that is ordinary practice of those skilled in the art to use the term 'patient' to describe data obtained in this manner." Applicant's arguments have been thoroughly considered but are not persuasive. First, while it may be ordinary practice to refer to an amniotic fluid sample obtained from around a fetus as a "patient" sample (with the patient being

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the fetus), the mother from whom the sample is obtained would also properly constitute a "patient" (specifically, the patient from whom the sample was actually obtained), and the specification does not actually indicate that the "patient" referred to therein is a fetus, or that the sample analyzed from said "patient" was amniotic fluid (as opposed to, e.g., another fluid obtained from a baby or adult with Down Syndrome). Further, while the response makes reference to declaratory evidence, Applicant has not actually provided declaratory evidence establishing, e.g., that the "patient" samples of the specification were in fact amniotic fluid samples taken from around fetuses that were later confirmed as having Down Syndrome. Applicant is further reminded that 35 USC 112, first paragraph requires that an invention be enabled as of the time the invention was made (i.e., as of the effective filing date of the application). Applicant's arguments are not persuasive.

### ***Conclusion***

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 571/272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Diana B. Johannsen", followed by a long, sweeping horizontal line that extends to the right.

Diana B. Johannsen  
Patent Examiner  
February 23, 2004